

BEFORE THE IOWA BOARD OF PHARMACY

RE:
Pharmacy License of

MERCY FAMILY PHARMACY REGENCY,
License No. 1138
Respondent.

CASE NO. 2017-159

**COMBINED STATEMENT OF CHARGES,
SETTLEMENT AGREEMENT, AND FINAL
ORDER**

COME NOW the Iowa Board of Pharmacy ("Board") and Mercy Family Pharmacy Regency ("Respondent"), 621 S Illinois Ave, Ste 101, Mason City Iowa 50401, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 155A, and 272C (2018), and 657 IAC chapter 36.

A. STATEMENT OF CHARGES

COUNT I

1. Respondent is charged with failing to comply with the current revision of USP Chapter 795 standards, specifically by failing to keep adequate master formulation records and compounding records, in violation of 657 IAC 20.3, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT II

2. Respondent is charged with failing to remove outdated drugs or devices from dispensing stock in violation of 657 IAC 8.8, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT III

3. Respondent is charged with failing to label compounded preparations in compliance with 657 IAC 20.19 and 20.20, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT IV

4. Respondent is charged with failing to document changes to the perpetual inventory record in a manner consistent with 657 IAC 10.18(3), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and (h), and 657 IAC 36.6(21) and (29).

B. FACTUAL CIRCUMSTANCES

5. Respondent's Iowa pharmacy license number 1138 is currently active through December 31, 2018.

6. Respondent dispensed compounded preparations that were made with expired ingredients.

7. A compliance officer visited the pharmacy in December of 2017 and discovered several incomplete compounding records. In January of 2018, Respondent underwent an inspection as a result of the prior visit.

8. The following deficiencies were discovered during the initial visit and subsequent inspection:

- a. There were several expired compounding ingredients on the shelves.
- b. The compounding logs were not accurate and were missing required information.
- c. A compounded preparation was not labeled with the names and amounts of active ingredients and did not have "compounded preparation" on the label.
- d. Batch preparation labeling was not applied to compounded syringes and lacked necessary information.
- e. The pharmacy's perpetual inventory system for Schedule II controlled substances did not allow changes to be tracked. Respondent had been previously been made aware of this issue during a routine inspection in October of 2016.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

9. The Board has jurisdiction over the parties and the subject matter of these proceedings.

10. Respondent admits the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

11. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

12. Respondent acknowledges that it has the right to be represented by counsel on this matter.

13. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

14. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

15. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

16. This Order shall not be binding as to any new complaints received by the Board.

17. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

18. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

19. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

20. Respondent shall be **INDEFINITELY RESTRICTED** from engaging in any compounding. If Respondent wishes to engage in compounding, Respondent may petition the Board for removal of this restriction. To have the restriction lifted, Respondent shall appear before the Board and demonstrate that the pharmacy has appropriate knowledge, policies and procedures, and staff training to comply with all applicable compounding standards.

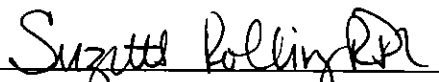
21. Respondent's license shall be placed on **PROBATION** for a period of two (2) years, subject to the following terms:

- a. Within sixty (60) days, Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars (\$5000). The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund.
- b. Respondent shall complete self-inspections on a monthly basis and submit documentation of each self-inspection at quarterly intervals to the Board. Board compliance officers may conduct on-site inspections at any time. Respondent shall work with Board compliance officers to ensure any deficiencies uncovered during a self-inspection or Board inspection are corrected in a timely fashion. Respondent's failure to correct deficiencies in a timely fashion may be considered a violation of this Order. Respondent shall submit documentation of the monthly self-inspections on a quarterly basis, with such reports being due no later than March 5th, June 5th, September 5th, and December 5th of each year.

- c. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- d. The civil penalty required to be submitted to the Board pursuant to paragraph 21a should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309. The documentation required to be submitted pursuant to paragraph 21b shall be emailed to Amanda.Woltz@iowa.gov.

22. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C, and 657 IAC chapter 36.

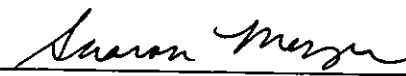
This Combined Statement of Charges, Settlement Agreement, and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 8th day of May, 2018.



MERCY FAMILY PHARMACY REGENCY
Respondent

By the signature above, Suzette Rolling acknowledges s/he is the Manager - Mercy Family Pharm. for Respondent and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 23 day of May, 2018.



Chairperson
Iowa Board of Pharmacy